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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/359,975	07/23/1999	DAVID B. WEINER	UPAP-0345	3521
34137	7590	03/23/2005	EXAMINER	
COZEN O'CONNOR, P.C. 1900 MARKET STREET PHILADELPHIA, PA 19103-3508			GUZO, DAVID	
			ART UNIT	PAPER NUMBER
			1636	

DATE MAILED: 03/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/359,975

Applicant(s)

WEINER ET AL.

Examiner

David Guzo

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 January 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 58, 59, 63, 64, 115-125 and 141-165 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 58, 59, 63, 64, 115-125 and 141-165 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 11/22/04
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Detailed Action

Obviousness Type Double Patenting Rejections

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 58-59, 63-64, 115-125 and 141-165 rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4, 6-14, 18-56 and 69-75 of U.S. Patent No. 5,981,505. Although the conflicting claims are not identical, they are not patentably distinct from each other because of reasons of record in the previous Office Action.

Claims 58-59, 63-64, 122-125 and 148-161 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 2-24 and 30-32 of U.S. Patent No. 5,817,637. Although the conflicting claims are not identical, they are not patentably distinct from each other because of reasons of record in the previous Office Action.

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Claims 148-154, 156-157, 162, 164-165 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-17 of U.S. Patent No. 5,830,876. Although the conflicting claims are not identical, they are not patentably distinct from each other because of reasons of record in the previous Office Action.

Claims 148-154, 156-157, 162 and 164-165 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4, 6-9 of U.S. Patent No. 5,593,972. Although the conflicting claims are not identical, they are not patentably distinct from each other because of reasons of record in the previous Office Action.

Claims 148-154, 156-157, 162 and 164-165 are directed to an invention not patentably distinct from claims 1-4, 6-9 of commonly assigned 5,593,972. Specifically, the claims are not patentably distinct for the reasons of record in the previous Office Action.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP § 2302). Commonly assigned 5,593,972, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c)

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and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications filed on or after November 29, 1999.

It is noted that current assignment data for the instant application is not available to the Office; however, the examiner assumes that the instant invention and the invention claimed in the 5,593,972 patent are currently commonly owned. If this is incorrect, applicants are required to inform the Office of the current assignment data for the instant application.

Applicants have not specifically traversed the above obviousness type double patenting rejections but instead have indicated that Terminal Disclaimers will be filed, as appropriate, upon indication of allowable subject matter.

35 USC 112, 1st Paragraph Rejections

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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Claims 115-121 and 141-165 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

This rejection is maintained for reasons of record in the previous Office Action and for reasons outlined below. It is noted that upon reconsideration of the rejection as applied to the composition claims (Claims 58-59, 63-64, 122-125) and given applicants' amendment to the composition claims deleting reference to "pharmaceutical" compositions and given applicants' arguments presented 1/7/05, the enablement rejection as applied to the instant composition claims is withdrawn. The rejection as applied to the instant method claims is maintained.

Applicants' arguments relating to enablement of the method claims are similar to the arguments filed in the response of 3/5/04. The examiner has addressed these arguments in the Office Action mailed 6/16/04 and will briefly address them again here.

Applicants argue that multiple uses are proposed or are well known in the art for the claimed methods of introducing DNA into cells of an individual or methods of inducing antibodies against an antigen in an individual. Applicants indicate that alternative methods of using the claimed methods are so well known as to preclude their recitation in the instant specification. Applicants then quote MPEP section (2164.01) with regard to enablement of an invention if any use is enabled when multiple

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uses are disclosed. Applicants assert that one of skill in the art would clearly know how to use the claimed **methods**.

Applicant's arguments filed 1/7/05 have been fully considered but they are not persuasive. First, it is again noted that the only uses disclosed in the instant application for the claimed method of introducing DNA into a cell in a individual or inducing an immune response to an antigen in an individual are for therapeutic purposes, that is induction of immunity to a pathogen or gene therapy for treatment of disease. The additional uses applicants indicate for a method of inducing an immune response in humans are not disclosed or suggested in the instant disclosure. Enablement for a claimed invention must be judged by whether the instant disclosure (and prior art) teaches the skilled artisan how to make and use the claimed invention without undue experimentation. As the only disclosed uses of the claimed methods are therapeutic in nature (i.e. immunization or gene therapy), enablement must be judged on whether applicants (and the prior art) have provided a disclosure sufficient to enable the skilled artisan to practice the claimed invention without having to practice undue experimentation. The examiner has previously made a *prima facie* case for non-enablement of the instant claims in the previous Office Action and applicants have not specifically traversed any of the examiner's statements concerning specific *Wands* Factors elucidated in the rejection.

Second, the section of the MPEP cited by applicants (2164.01) is relevant to composition claims, not method claims. Clearly MPEP 2164.01(c) recites that **in evaluating composition claims for compliance with the enablement requirement,**

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where multiple uses are disclosed, enablement for any of the disclosed uses satisfies the enablement requirement for the claimed composition. In the instant case, only one use is taught for the claimed methods and the examiner has previously made a *prima facie* case for non-enablement. With regard to the alleged multiple uses of the claimed methods of introducing DNA into cells in an individual or inducing an immune response to an antigen in an individual, none of these uses are disclosed in the specification. Indeed, the alleged multiple uses contemplated by applicants are different methods than those claimed. For example, applicants assert that antibodies produced as a result of practicing the claimed invention can be removed from the host and used for inducing passive immunity in another individual or can be used as diagnostic agents, etc. These uses are not uses of the **claimed invention**, but instead are different inventions themselves which use a result emanating from practice of the claimed invention in order to practice another unrelated invention. The claimed invention is a method for inducing an immune response in an individual, not a method for inducing passive immunity in a host by administering antibodies or a diagnostic method, etc.

For the reasons above and for reasons of record, the rejection is maintained.

No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Guzo, Ph.D., whose telephone number is (571) 272-0767. The examiner can normally be reached on Monday-Thursday from 8:00 AM to 5:30 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel, Ph.D., can be reached on (571) 272-0781. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David Guzo
March 10, 2005


DAVID GUZO
PRIMARY EXAMINER